

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

CASE NO. 4:24-CR-00010 RLW/SPM

UNITED STATES OF AMERICA

vs.

MOHD AZFAR MALIK, M.D.

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**REPLY IN SUPPORT OF DR. MALIK’S MOTION TO DISMISS  
THE DRUG TRAFFICKING COUNTS (DOC. 54)**

The Government charged Dr. Malik with unlawfully conspiring to distribute controlled substances (Count 1), with unlawful distribution of controlled substances (Count 3–14), and with maintaining a drug involved premises (Count 22). We filed a motion to dismiss these counts because the Government did not allege a crucial element – that Dr. Malik distributed the medication without a legitimate medical reason. Recognizing the force of this argument and without a real response, the Government says that it did not need to allege this element because it did not charge Dr. Malik with distribution; instead it says that the “precise crime” it actually charged was “the unsupervised **dispensation** of controlled substances.”

But that’s not what the Government actually charged:

**COUNT 1**  
**Conspiracy to Illegally **Distribute** Controlled Substances and**  
**to Maintain a Drug-Involved Premises**  
**21 U.S.C. § 846**

The Grand Jury further charges that:

33. The above allegations are incorporated by reference as if fully set out herein.

34. Beginning in or about December 2020, and continuing to at least in or about March 2023, in St. Louis, Missouri, in the Eastern District of Missouri and elsewhere, the defendants,

ASIM MUHAMMAD ALI, M.D., and  
MOHD AZFAR MALIK, M.D.

knowingly and intentionally combined, conspired, confederated, and agreed together and with each other, and with other persons known and unknown to the Grand Jury, to commit the following offenses against the United States: to **distribute and possess with the intent to distribute** ketamine and esketamine, both schedule III controlled substances, in violation of Title 21, United States Code, Sections 841(a)(1), and to maintain drug-involved premises by managing and controlling a place and knowingly and intentionally making it available for use for the purpose of unlawfully storing and **distributing** ketamine and esketamine, both schedule III controlled substances, in violation of Title 21, United States Code, Sections 856(a)(2), all in violation of 21 U.S.C. § 846.

Count 1 is pretty clear – it charges Malik with a conspiracy to “**distribute** and possess with intent to **distribute** ketamine and esketamine.” Not a conspiracy to dispense or administer).

So too with the other counts:

**COUNTS 3 THROUGH 14**  
**Illegal Distribution of a Controlled Substance**  
**21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2**

The Grand Jury further charges that:

58. The above allegations are incorporated by reference as if fully set out herein.

59. On or about the dates listed below, in St. Louis, Missouri, in the Eastern Division of the Eastern District of Missouri and elsewhere, the defendants,

ASIM MUHAMMAD ALI, M.D., and  
MOHD AZFAR MALIK, M.D.

aided and abetted by, and aiding and abetting each other, and others known and unknown to the Grand Jury, knowingly and intentionally distributed the substances listed below, all of which are schedule III controlled substances, in violation of Title 21, United States Code, Section 841(a)(1) and Title 18, United States Code, Section 2, in that Dr. Ali, who had no DEA registration, administered the substance indicated outside of the presence of and without the direct supervision of Dr. Malik, under whose DEA registration number the controlled substances were administered:

Count	Patient Initials	Date of Administration	Controlled Substance/ Administration Type
3	S.T.	2/6/2021	Ketamine/Intravenous infusion
4	C.G.	2/6/2021	Ketamine/Intravenous infusion
5	T.A.	12/23/2021	Spravato (esketamine)/Nasal spray
6	T.A.	12/31/2021	Spravato (esketamine)/Nasal spray
7	J.C.	10/15/2022	Ketamine/Intravenous infusion
8	K.B.	10/15/2022	Ketamine/Intravenous infusion
9	S.T.	10/22/2022	Ketamine/Intravenous infusion
10	T.H.	10/22/2022	Ketamine/Intravenous infusion
11	R.B.	10/22/2022	Ketamine/Intravenous infusion
12	C.J.	10/22/2022	Ketamine/Intravenous infusion
13	O.O.	10/29/2022	Ketamine/Intravenous infusion
14	J.C.	10/29/2022	Ketamine/Intravenous infusion

All in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2.

Perhaps that Government is focused on the word “administered” in Counts 3–14, but that is only the alleged manner that the supposed distribution crime was carried out. The charge itself in these counts is that Malik “knowingly and intentionally **distributed** the substances...”

**COUNT 22**  
**Maintaining Drug-Involved Premises**  
**21 U.S.C. § 856(a)(2) and 18 U.S.C. § 2**

The Grand Jury further charges that:

62. The above allegations are incorporated by reference as if fully set out herein.

63. Beginning in or about December 2020 and continuing through in or about March 2023, in St. Louis, Missouri, in the Eastern Division of the Eastern District of Missouri, the defendants,

ASIM MUHAMMAD ALI, M.D., and  
MOHD AZFAR MALIK, M.D.

aided and abetted by, and aiding and abetting each other, and others known and unknown to the Grand Jury, did unlawfully manage and control a place located at 5000 Cedar Plaza Parkway, Suite 220, St. Louis, Missouri 63128 and did knowingly and intentionally make that place available for use for the purpose of unlawfully storing and **distributing** controlled substances, namely, ketamine and esketamine, in violation of Title 21, United States Code, Section 856(a)(2).

In each of these drug trafficking counts, the Government charged Dr. Malik with the ***distribution*** of controlled substances. Because the Government alleged only illegal distribution, the Indictment must be dismissed as it does not allege that the distribution was done without a legitimate medical purpose. The Government cannot proceed on a different theory.

The drug trafficking statute, 21 U.S.C. §§ 841(a)(1), provides that, except as authorized, it shall be unlawful for any person knowingly or intentionally “to manufacture, ***distribute, or dispense***, or possess with intent to manufacture, ***distribute, or dispense***, a controlled substance[.]” (Emphasis added.) The statute thus makes an express distinction between crimes that involve ***distributing*** controlled substances and crimes that involve ***dispensing*** controlled substances. This distinction is also found in the definitional section of Title 21, which provides separate definitions for “distribute” and “dispense.” Significantly, the definition of “distribute” expressly excludes the terms dispensing and administering: “[t]he term ‘distribute’ means to deliver (***other than by administering or dispensing***) a controlled substance or a listed chemical.” 21 U.S.C. § 802(11) (emphasis added).

The Government goes to great lengths in its motion to distinguish between “distributing” on the one hand and “administering or dispensing” on the other. The Government needs to make this distinction or the Indictment cannot survive scrutiny: if Dr. Malik is charged with distribution, the Indictment fails to state a claim because it lacks the essential element of no legitimate medical necessity. The Government concedes that when an Indictment charges distribution, it must also allege that there was no legitimate medical purpose. (Response, 13–14). The Indictment does not allege that necessary element.

Realizing this problem, the Government says that for an illegal ***dispensing*** case, it need not prove that the doctor acted without a legitimate medical need. We disagree with that proposition. But the Court need not engage in this debate because

Count 1 does **not** allege that Dr. Malik conspired to **dispense** (or administer) ketamine and esketamine, in violation of 21 U.S.C. §§ 841(a)(1) and 846, even though distributing and dispensing are separate and distinct ways of violating those statutes.<sup>1</sup> The government, therefore, may not ask a jury to convict Dr. Malik on a theory that he conspired to or aided and abetted a violation involving the dispensing of ketamine or esketamine. *See Stirone v. United States*, 361 U.S. 212, 217 (1960) (“[A] court cannot permit a defendant to be tried on charges that are not made in the indictment against him.”); *see also United States v. Cancelliere*, 69 F.3d 1116, 1121 (11th Cir. 1995) (citing *Stirone*) (“A jury instruction that constructively amends a grand jury indictment . . . violates a defendant’s constitutional right to be tried on only those charges presented in a grand jury indictment and creates the possibility that the defendant may have been convicted on grounds not alleged in the indictment.”). So too with Counts 3–14 and 22. The term “distribute” expressly excludes the term “administering,” meaning that it was legally impossible for Dr. Malik or Dr. Ali to distribute a controlled substance by administering it to another person or to control a place for the purpose of distributing a controlled substance by administering it.

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<sup>1</sup> The Government sometimes says that Dr. Malik illegally dispensed the medicine through Dr. Ali’s administration of it. To dispense means “to deliver a controlled substance to an ultimate user or research subject by, **or pursuant to the lawful order** of, a practitioner, including the prescribing and administering of a controlled substance.” 21 U.S.C. § 802(10). Because Dr. Malik issued a lawful order regarding the medicine in this case (i.e. it was for a legitimate medical purpose), he cannot be found guilty of unlawfully dispensing it. The Government complains that he did not properly supervise Dr. Ali when he administered the ketamine, but again, that is a regulatory concern, not a criminal one.



Given the express exclusion of “administering” in the definition of “distribution,” each of the drug trafficking counts must be dismissed for the reasons we explain in our motion. The bottom line is that Dr. Malik was not charged with illegally *dispensing* ketamine and esketamine. Perhaps more fundamentally, the error reveals the fundamental flaws in the Government’s thinking in this case: in its rush to bring an additional Indictment against Dr. Ali, the Government has put together a legally bungled drug distribution case that swept in Dr. Malik based on what are—at worst—regulatory foot faults. The Court should not allow the Government to prosecute crimes that are not charged in the Indictment.

Even if the Indictment could be read to have charged Dr. Malik with illegally dispensing, the Motion should still be granted. It may be true, as the Government says, that not everything a doctor does is protected from liability.<sup>2</sup> However, even on the Government’s uncharged “unsupervised dispensation” theory, the Indictment

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<sup>2</sup> To make its point, the Government cites *United States v. Moore*, 423 U.S. 77, 135 (1975). But that *Moore* case does not have a page 135 or contain the cited quotation. The Government must have intended to cite *United States v. Moore*, 423 U.S. 122, 135 (1975). That case does note that the CSA makes all “transactions outside the legitimate distribution chain illegal.” However, the case fails to make the Government’s point, as the doctor defendant in *Moore* faced allegations of “unlawfully dispensing and **distributing** controlled substances” (emphasis added). The doctor’s actions exceeded the bounds of “professional practice” where the defendant gave inadequate exams, administered methadone outside of the clinic, gave as much of the controlled substance as the patient demanded, charged only per number of tablet and not for medical services, and did not take steps to avoid misuse or diversion. *Moore* at 143–144. The *Moore* case supports Dr. Malik’s position because the Indictment charges “distribution” without alleging that the required element that Dr. Malik prescribed the controlled substances knowing it was for no legitimate purpose.

fails to state a claim because Dr. Malik *was* authorized to dispense controlled substances as he had a DEA registration. He is, therefore, protected from liability.

The Government identifies Dr. Malik's crime as the "*unsupervised* dispensation of controlled substances by anyone without a Drug Enforcement Administration (DEA) registration. But Dr. Malik had a valid DEA registration, permitting him to dispense Schedule III controlled substances. The statute does not criminalize every regulatory infraction related to dispensation. Improper supervision or storage is simply not a crime if the dispensation was done for a legitimate medical purpose.

The Government argues that 21 C.F.R. § 1306.04 is an inapplicable prescription regulation and that authoritative case law does not require a lack of legitimate medical purpose. The Government is wrong.

Title 21 U.S.C. § 841 makes it a federal crime, "[e]xcept as authorized[,] ... for any person knowingly or intentionally ... to manufacture, distribute, or dispense ... a controlled substance[.]" (Emphasis added). The Supreme Court recognized in *Ruan v. United States*, 597 U.S. 450, 454 (2022), that the "authoriz[ation]" referred to in the statute is provided for by regulation. ("Registered doctors may prescribe these substances to their patients. But, as provided by regulation, a prescription is only authorized when a doctor issues it 'for a medical purpose ... acting in the usual course of his professional practice,' *citing* 21 C.F.R. § 1306.04(a)(2021)). It is the Supreme Court, not Dr. Malik, that applied the authorization provided for in 21 C.F.R. § 1306 to the acts of "manufactur[ing], distribut[ing], or dispens[ing]" a controlled substance.



*Ruan* at 454. In each of the *Ruan* consolidated cases, a doctor was convicted under § 841 for “dispensing” controlled substances not “as authorized.” *Id.* These doctors were not charged with distribution. And yet, contrary to the Government’s argument, the Court held that the Government was required to prove that the defendants “knew that he or she was acting in an unauthorized manner, or intended to do so.” *Id.*

*Ruan* is a case about “841’s exception from the general prohibition on dispensing controlled substances contained in the phrase [except as authorized].” *Ruan* at 454. *Ruan* is not limited to cases involving prescribing controlled substances, as the Government contends. It is a case about “dispensing.” Should the Court permit the Government to proceed on its uncharged theory, it still must show that Dr. Malik acted outside of his authorization (i.e. for not legitimate medical purpose).

This case is easily distinguishable from every case that the Government cites in support of its theory that they can prosecute Dr. Malik, a DEA-registered doctor, for the alleged unsupervised dispensation of a controlled substance. In *United States v. Blanton*, the physician’s DEA registration did not permit him to dispense the drugs at issue in the case. 730 F.2d 1425, 1427 (11th Cir. 1984). Therefore, that doctor was “not authorized to dispense” the drug at issue, *id.* at 1429, unlike Dr. Malik who was authorized to dispense Schedule III controlled substances. More to the point, the court specifically distinguished the *Blanton* doctor from the physician in *Moore* by noting that *Moore* involved the question of whether a physician could be prosecuted for dispensing drugs *for which he was registered*. *Id.* at 1430. The conviction in *Blanton* hinged on the doctor’s dispensation “for other than a legitimate medical

purpose.” he purchased nearly 300,000 tablets of a controlled substance he was not registered to dispense, prescribed that drug to over 3,000 patients in less than a year, and those patients included a 9-year-old child. *Id.* at 1428. Unlike Dr. Malik, the defendant in *Blanton* acted outside of his authorization, like a drug trafficker.

Similarly, *United States v. Jones*, 816 F.2d 1483 (10th Cir. 1987), and *United States v. Cheek*, 592 Fed. Appx. 179 (6th Cir. 2014), are inapplicable to the facts at hand. The defendant in *Jones* was a physician’s assistant who was not registered at all with the DEA, called in false prescriptions to pharmacies, and used the drugs for illegal street sales. *Jones* at 1484–1485. The defendant in *Cheek* also did not have a DEA registration – her registration was revoked following a conviction for health care fraud and her practice targeted drug addicts. *Cheek* at 181–182.

Dr. Malik had a valid DEA registration, which allowed him to distribute *and* dispense the controlled substances at issue, and separates him from every case relied on by the Government. The Government has not found a case where the federal drug trafficking statute was used to charge a doctor who was authorized to distribute and dispense controlled substances but was alleged to have improperly supervised the administration of the medication.<sup>3</sup> And for good reason -- that’s a regulatory issue (at most), not a criminal one. Under the Government’s reading, any doctor who

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<sup>3</sup> The Government takes the strange position that “Malik does not dispute that the Indictment sufficiently alleges that he acted outside the usual course of professional practice.” ECF 64-1 at 17 n. 8. But Dr. Malik unequivocally disputes that the Indictment sufficiently alleges that he acted outside the usual course of professional practice. At most, the Indictment charges that he failed to properly supervise Dr. Ali’s administration of ketamine and Spravato, which does not satisfy *Ruan* or 841.

commits a regulatory infraction will be subjected to criminal prosecution under the drug trafficking statutes. We respectfully ask this Court to put an end to this unjust and unprecedented prosecution.

Respectfully submitted,

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